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| PPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|---------------|-------------------------|---------------------|-----------------|
| 10/025,732 | 12/19/2001 | William M. Pardridge | 0180.0029 | 8416 |
| 75 | 90 06/03/2003 | | | • |
| David J. Oldenkamp, Esq. Shapiro, Borenstein & Dupont LLP Suite 700 | | | EXAMINER | |
| | | | LAMBERTSON, DAVID A | |
| 233 Wilshire Bo Santa Monica, O | | | ART UNIT | PAPER NUMBER |
| , | | | 1636 | 4 |
| | | DATE MAILED: 06/03/2003 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|---|-------------------------|---|--|--|--|
| Office Action Summary | | 10/025,732 | PARDRIDGE, WILLIAM M. | | | |
| | | Examiner | Art Unit | | | |
| | | David A. Lambertson | 1636 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM | | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | Decreasing to accompanies than (a) filed as 40.5 | 2000 | | | | |
| 1)⊠ | Responsive to communication(s) filed on 19 E | is action is non-final. | | | | |
| 2a)☐ | , | | proposition as to the morits is | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-24 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| | Claim(s) is/are objected to. | alastian requirement | | | | |
| 8) Claim(s) <u>1-24</u> are subject to restriction and/or election requirement. Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 2) Notic | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Inform | nary (PTO-413) Paper No(s) nal Patent Application (PTO-152) | | | |

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1. 1. 3

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 23 and 24, drawn to a receptor specific liposome and pharmaceutical compositions thereof, classified in class 424, subclass 1.21.
- II. Claims 11-22, drawn to a method of delivering a therapeutic gene to ocular cells, classified in class 435, subclass 458.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced using another materially different product, such as the use of a viral vector.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, these inventions require non-patent literature searches that are not co-extensive, hence a simultaneous search of each invention would be burdensome. As a result, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson April 7, 2003

PRIMARY EXAMINER